



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,052	03/24/2004	Richard S. Blumberg	18989-033	4208

30623 7590 01/16/2007  
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY  
AND POPEO, P.C.  
ONE FINANCIAL CENTER  
BOSTON, MA 02111

EXAMINER
----------

KOSAR, ANDREW D

ART UNIT	PAPER NUMBER
----------	--------------

1654

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/16/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/808,052

Applicant(s)

BLUMBERG, RICHARD S.

Examiner

Andrew D. Kosar

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8, 16, 17, 19-23, 34-37, 40-46 and 49-79 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 16, 17, 19-23, 34-37, 40-46 and 49-79 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/11/05</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION*****Response to Amendments/Arguments***

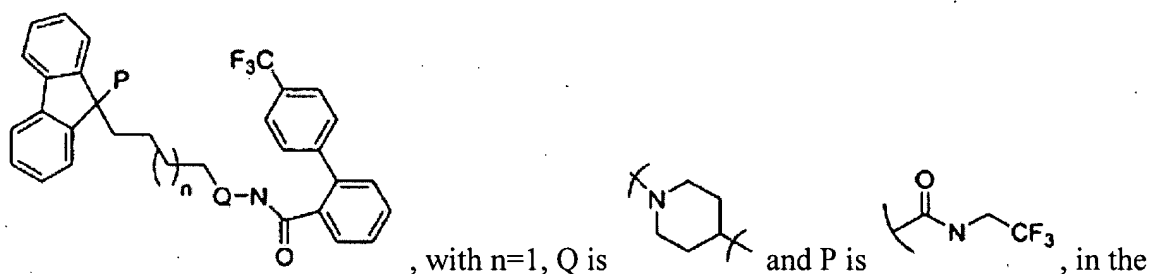
Applicant's amendments and arguments filed May 16, 2006 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on November 11, 2006 has been considered.

***Election/Restrictions***

Applicant's election with traverse of Group IV, and the species



response filed October 3, 2006 is acknowledged.

In the restriction requirement of August 1, 2006, Applicant was clearly advised that, "Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention." (*Restriction, page 6*).

Art Unit: 1654

In the response Applicant has stated, "The methods of the invention have one effect— inhibiting inflammation... The response is similar regardless of the tissue undergoing the inflammation. The steps of the methods are identical, the mechanism is identical (activation of a CD1-restricted T-cell) and the class of compounds used to reduce CD1-mediated inflammation is identical regardless of tissue type. Therefore practicing one method for one tissue type is exactly the same as practicing it for another tissue type." (*Remarks, page 3*).

Thus Applicant has admitted on the record that the practice of "one method for tissue type is exactly the same as practicing it for another tissue type." Accordingly, the restriction requirement of August 1, 2006 is hereby withdrawn and this admission has been used in the rejection under 35 U.S.C. § 103(a) of the other invention. Additionally, in view of Applicants admission, that "the mechanism is identical (activation of a CD1-restricted T-cell) and the class of compounds used to reduce CD1-mediated inflammation is identical regardless of tissue type," the election of species is also hereby withdrawn.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1654

**Claims 1-8, 16, 17, 19-23, 34-37, 40-46 and 49-79** are rejected under 35 U.S.C. 103(a) as being unpatentable over GREGG (WO 98/50028 A1; PTO-892, 11/16/05).

The instant claims are generally drawn to inhibition of inflammation, inhibition of CD1-mediated inflammation, and inhibition of tissue inflammation.

Gregg teaches the elected species, identified as BMS-201,238 in a pharmaceutical composition (claim 10, page 47). It is noted by the examiner that BMS-201,038 (page 27), is the same compound by structure, and is claimed in a pharmaceutical composition (claim 21, page 55), and is identified in the specification as a 'most preferred' compound for practicing the invention (page 27).

Gregg teaches a method of lowering serum lipid levels, cholesterol and/or triglycerides, inhibiting and/or treating hyperlipidemia, hyperlipemia, hyperlipoproteinemia, hypercholesterolemia and/or hypertriglyceridemia, and/or preventing, inhibiting or treating atherosclerosis, pancreatitis, hyperglycemia or obesity in a mammalian species, comprising administering the compounds of claim 1 to a patient in need in a therapeutically effective amount (claims 22 and 23).

Atherosclerosis and diabetes (hyperglycemia) are art recognized to have inflammatory components (e.g. *REGAN-US Patent 6,080,763, column 3, lines 3-5; SALZMAN- US 2001/0053763 A1, page 3, [0040]*).

Gregg further teaches that the oral doses of the drug are 0.01 mg/kg to about 100 mg/kg, but preferably from 0.1 mg/kg to 75 mg/kg, and parenteral administration being preferred at 0.005 mg/ to about 8 mg/kg. (page 34). Additionally, it is noted that cardiac inflammation 'includes' atherosclerosis (page 18, instant specification).

Art Unit: 1654

Therefore, because Applicant has admitted on the record that the practice of "one method for tissue type is exactly the same as practicing it for another tissue type" it is deemed that the methods are obvious under 35 USC § 103(a). Additionally, because Applicant has admitted that "the mechanism is identical (activation of a CD1-restricted T-cell) and the class of compounds used to reduce CD1-mediated inflammation is identical regardless of tissue type", the methods being practiced with any inhibitor of MTP is obvious under 35 USC § 103(a).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

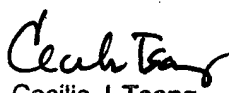
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

Art Unit: 1654

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Andrew D. Kosar, Ph.D.  
Patent Examiner  
Art Unit 1654

  
Cecilia J. Tsang  
Supervisory Patent Examiner  
Technology Center 1600